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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,481	03/10/2004	John G. Stark	3223.01US02	3292
24113	7590	04/05/2006	EXAMINER	
PATTERSON, THUENTE, SKAAR & CHRISTENSEN, P.A.			REIMERS, ANNETTE R	
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MINNEAPOLIS, MN 55402-2100			3733	

DATE MAILED: 04/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/797,481	STARK, JOHN G.	
	Examiner	Art Unit	
	Annette R. Reimers	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 17-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 17-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claim 13 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Independent claim 12 has been amended to include the screw comprising a biocompatible material.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by the Kambin (U.S. Patent Number 6,175,758).

Kambin discloses a kit comprising an unthreaded pin, 56, a threaded, cannulated, self-tapping screw, 58, a cutting guide, 126, a drill bit, 38 and a cannula 124 (see Figures 2, 4-6; 14 and 17). The screw has a central canal for immobilization of a sacroiliac joint with a taper of at least about 1 degree and a dimension suitable for insertion into the sacroiliac joint of a human patient (see Figures 6 and 8).

With regard to the statement of intended use and other functional statements, e.g. "dimension suitable for insertion into the sacroiliac joint of a human patient", they do

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not impose any structural limitations on the claims distinguishable over Kambin, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claims 12-20 are rejected under 35 U.S.C. 102(b) as being anticipated by the Bowman et al. (U.S. Patent Number 4,950,270).

Bowman et al. disclose a biocompatible, fluted screw, 10, with a shaft with threads, 26, and a tip, 24, and a central canal for immobilization of a sacroiliac joint, wherein the shaft has a taper of at least about 1 degree and a dimension suitable for insertion into the sacroiliac joint of a human patient (see Figures 1 and 2 and column 3, lines 5-12).

With regard to the statement of intended use and other functional statements, e.g. "dimension suitable for insertion into the sacroiliac joint of a human patient", they do not impose any structural limitations on the claims distinguishable over Bowman et al., which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the

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subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claims 21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by the Cain (U.S. Patent Number 5,334,205).

Cain discloses a method for immobilizing a patient's sacroiliac joint comprising inserting an immobilization/fusion element into a drilled area of the sacroiliac joint through a cannula that is placed through an incision formed in the patient, drilling a region at the sacroiliac joint through the cannula, and placing a guide pin through the cannula (see column 4, lines 4-48).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kambin (U.S. Patent Number 6,175,758) in view of Bowman et al. (U.S. Patent Number 4,950,270).

Kambin discloses the claimed invention except for the screw being associated with or coated with a biologically active agent. Bowman discloses a screw and teaches

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that the screw is constructed and/or coated with a biocompatible material and teaches the use of biocompatible material to allow for permanent or long term emplacement in association with cancellous bone and soft tissues and to promote osteointegration (see Column 3, lines 13-17). It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Kambin with the screw being associated with or coated with a biologically active agent in view of Bowman, in order to allow for permanent or long term emplacement in association with cancellous bone and soft tissues and to promote osteointegration.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kambin (U.S. Patent Number 6,175,758).

Kambin discloses the claimed invention except for the screw having a taper of at least about 1 degrees. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the device of Kambin having a taper of the screw of at least about 1 degree, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bowman et al. (U.S. Patent Number 4,950,270).

Bowman et al. disclose the claimed invention except the taper of the screw being from about 2 degrees to about 30 degrees, the length of the screw being from about 4 inches to about 10 inches and the widest thickness of the screw being from about 1.4mm to about 16mm. It would have been an obvious matter of design choice to one

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skilled in the art at the time the invention was made to construct the device of Bowman et al. having the taper of the screw being from about 2 degrees to about 30 degrees, the length of the screw being from about 4 inches to about 10 inches and the widest thickness of the screw being from about 1.4mm to about 16mm since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cain (U.S. Patent Number 5,334,205) in view of Chang et al. (U.S. Patent Publication Number 20020099288)

Cain discloses the claimed method except for the use of real time imaging. Chang et al. discloses the use of real time imaging in order to guide the placement and orientation of an object (see paragraph 0013 and paragraph 0032). It would have been obvious to one skilled in the art at the time the invention was made to incorporate in the method of Cain the use of imaging in view of Chang et al., in order to guide the placement and orientation of the pin.

Response to Arguments

Applicant's arguments filed on January 13, 2006 have been fully considered but they are not persuasive. In response to applicant's argument that the Kambin and the Bowman references are not directed to a screw with a taper of at least about 1 degrees and appropriate dimensions for implantation into the sacroiliac joint of a human patient, it is noted that the law of anticipation does not require that the reference "teach" what

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the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

In addition, regarding the Kambin reference disclosing a screw with a taper of at least about 1 degrees, as stated above, it would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the device of Kambin having a taper of the screw of at least about 1 degree, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Furthermore, examiner respectfully disagrees with applicant regarding the Bowman et al. reference, since the reference discloses a screw with a taper of at least about 1 degrees (see column 3, lines 5-12).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO 892 for art cited of reference.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette R. Reimers whose telephone number is (571) 272-7135. The examiner can normally be reached on Monday-Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AR

MR


EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER